M E M O R A N D U M

TO: Terry L. Noah, M.D.
Dept. of Pediatrics
CB # 7220
Carolina Campus

FROM: Committee on the Protection of the Rights of Human Subjects

DATE: February 5, 2002

SUBJECT: 01-PED-632 Characterization of Mucus and Mucins in Bronchoalveolar Lavage Fluids From Infants with Cystic Fibrosis

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The Committee on the Protection of the Rights of Human Subjects, at its February 4, 2002 meeting, voted to **DISAPPROVE** the above-referenced proposal. Reasons for this decision are detailed below. You have the option of appealing this decision. Any resubmission for appeal must include all materials and copies required with the original submission, and all appeals must be considered at a convened meeting of the IRB.

To approve research in children, conditions outlined in 45 CFR 46, Subpart D must be satisfied.

46.404: Bronchoscopy is a procedure which represents greater than minimal risk, so this research cannot be approved under this category.

46.405: Approval in this category requires that research involving greater than minimal risk presents the prospect of direct benefit to the individual subjects. The committee was not convinced of the prospect of direct benefit, especially since the research requires 3 bronchoscopies. Bronchoscopy in an asymptomatic infant is not indicated. Moreover, exculsion of children with any signs of acute infection or respiratory symptoms would appear to tip the scales away from those who might benefit from detection of hidden infections. The committee was also concerned about resistance to antibiotics with early treatment in asymptomatic infants. Is it proven or accepted that antibiotic treatment for bacterial infections in asymptomatic cystic fibrosis patients is beneficial?

46.406: Approval in this category is not possible since bronchoscopy represents more than a minor increase over minimal risk.

46.407: The IRB feels that the research presents a reasonable opportunity to further the understanding of pulmonary disease in cystic fibrosis, but cannot be approved under the three sections outlined above. The research should therefore be reviewed by OHRP, acting on behalf of the Secretary of DHHS. Our office would be happy to help you in your submission to OHRP.